

overcome the said rejection. Therefore, reconsideration of Claims 4-18, 22-55, 61 and 62, as amended, is respectfully requested.

Claim Rejection - 35 USC §112

The Examiner has rejected Claims 12-14, 16, 45, 48, 50, 52, 56, 59 and 60 under 35 USC §112, second paragraph, because they contain trademarks/trade names. Applicant has amended the claims to include the chemical name of the trademarked compounds Eudragit NE30D, Avicel, Eudragit RS and Eudragit RL, in order to advance the prosecution of the instant application. Therefore, reconsideration of the claims is respectfully requested. However, Applicant respectfully submits that these trademarks are well known in the industry and a person in the field reading these names would clearly understand what the compound is. Furthermore, the following are examples of patents which have issued with these trademarks in the claims. For Eudragit see Schedule "C", for Avicel see Schedule "D".

Claims 1, 2 and 56 have been rejected under 35 USC §112, second paragraph, since the phrase "540 mg or more", the Examiner purports, is considered vague. Applicant has corrected the phrase in Claims 1, 2 and 56. Therefore, reconsideration of these claims is respectfully requested.

Furthermore, Claim 9 has been rejected under 35 USC §112, second paragraph, as being indefinite. Applicant has re-written Claim 9 as suggested by the Examiner and Applicant thanks the Examiner for her suggestion. Therefore, reconsideration of Claim 9 is respectfully requested.

Claims 11, 15 and 45 have been rejected under 35 USC §112, second paragraph, for lack of antecedent basis in the claim. Applicant has amended the claim, namely corrected the limitation "bead" in the claims by replacing "bead" with "microgranule". Therefore, reconsideration of Claims 11, 15 and 45 is respectfully requested.

Claims 12, 13, 18, 44, 45, 50, 52, 56 and 59 have been rejected under 35 USC §112, second paragraph, based on the phrase "such as". Applicant has amended said claims by deleting the phrase "such as" in order to overcome said rejection. Reconsideration of the claims is respectfully requested.

Claim 18 has been rejected under 35 USC §112, second paragraph, based on the phrase "or the like". Applicant has deleted the phrase "or the like", and therefore, reconsideration of Claim 18 is respectfully requested.

Furthermore, the Examiner has rejected Claim 18 under 35 USC §112, second paragraph, as being indefinite since the phrase "higher pH regions" is considered vague and the appropriate correction is required. Applicant respectfully submits that persons skilled in the art would know what the phrase "higher pH regions" mean, specifically when read in context with "of the gastrointestinal tract of the intestine at which pH diltiazem is much less soluble". When read in context, this phrase "high pH regions" is, indeed, definite and clear. Therefore, reconsideration is respectfully requested.

The Examiner has rejected Claim 44 under 35 USC §112, second paragraph. Applicant has amended the phrase to include "selected from the group consisting of". Therefore, reconsideration of Claim 44 is respectfully requested.

Furthermore, the phrases as spelled out in pages 5 and 6 of Paper #6 of the United States Patent and Trademark Office in Claim 44 have been amended and, therefore, reconsideration of Claim 44 is respectfully requested.

Claim rejections 35 USC §102 and §103

The Examiner has rejected the claims under 35 U.S.C. §102 (anticipation) and other claims under 35 U.S.C. §103 (obviousness) on the basis of two references: Geoghegan European Patent Application 856,313 (the "'313 Patent") and Deboeck WO93/00093 (the "'093 Patent").

Applicable Legal Principles

Before proceeding further and dealing with the Grounds of Rejection of the Examiner and specifics of the prior art, Applicant wishes to bring to the Examiner's attention the following brief statements with respect to what it respectfully submits are the applicable legal principles in this case.

A generic formula which encompasses a vast number of compounds does not describe and thus anticipate, all compounds embraced therein merely because they are within the scope of the formula. In re Peterine et al. (CCPA 1962) 301 F2d 676, 133 USPQ 275; E.I. duPont de Nemours & Co. v. Ladd, Comr. Pats. (CADC 1964) 328 F2d 547, 140 USPQ 297. There can be no anticipation where the reference is so broad that the likelihood of arriving at the claimed composition would be the same as discovering the combination of a safe by an inspection of its dials, Ex parte Garvey (POBA 1939) 41 USPQ 583; Ex parte Starr (POBA 1938) 44 USPQ 545, nor is anticipation made out by a hindsight selection based on an applicant's disclosure of variables of a broad generic disclosure. In re Ruschig et al. (CCPA 1965) 343 F2d 965, 145 USPQ 274.

Further, a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. Dow Chem. Co. v. American Cyanamid Co. (CAFC 1987) 816 F2d 617, 2 PQ2d 1350; In re Grasseli et al. (CAFC 1983) 713 F2d 731, 218 USPQ 269; In re Dow Chemical Co. (CAFC 1988) 837 F2d 469, 5 PQ2d 1529. All prior art in analogous fields of endeavor must be considered and apparently conflicting references must be weighed for the power of their combined teachings to suggest a solution to an artisan of ordinary skill. In re Young (CAFC 1991) 927 F2d 588, 18 PQ2d 1089.

The "picking and choosing" and combining of references in the rejection clearly presents a case of an improper hindsight reconstruction. An improper hindsight reconstruction is one in which a rejection is construed as having been taught from isolated teachings of the prior art without considering the overall context within which those teachings are presented. Obviousness under 35 U.S.C. 103 must rest on a factual basis and these facts must be interpreted without

hindsight reconstruction of the invention from the prior art. See e.g. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975), *In re Rice*, 178 U.S.P.Q. 478 (C.C.P.A. 1973), and *In re Warner et al*, 154 U.S.P.Q. 173 (C.C.P.A. 1967).

Likewise, the courts have long held that "obvious to try" is not the standard of 35 U.S.C. 103 and not the test of patentability, and further that it is impermissible within the framework of 35 U.S.C. 103 to "pick and choose" from parts of reference to construct a rejection. See e.g. *In re Lunsford*, 148 U.S.P.Q. 721 (C.C.P.A. 1966), *In re Dien*, 152 U.S.P.Q. 550 (C.C.P.A. 1967), *In re Lindell*, 155 U.S.P.Q. 521 (C.C.P.A. 1967), *In re Marzocchi et al*, 169 U.S.P.Q. 367 (C.C.P.A. 1971), *In re Kamm et al*, 172 U.S.P.Q. 298 (C.C.P.A. 1972), *In re Antonie*, 195 U.S.P.Q. 6 (C.C.P.A. 1977), *In re Goodwin et al*, 198 U.S.P.Q. 1 (C.C.P.A. 1978), and *In re Yates*, 211 U.S.P.Q. 1149 (C.C.P.A. 1981).

When an attempt is made to change a single reference, a prima facie case of obviousness has not been established if the single reference does not teach the source of the problem, and the recognition of the source of the problem is what is unobvious. *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 US 45 (1923); *In re Sponnoble*, 405 F.2d 578, 160 USPQ 237 (CCPA 1969); *In re Peehs*, 612 F.2d 1287, 204 USPQ 835 (CCPA 1980).

The systematic investigation of nonobviousness includes as relevant evidence the objective indicia of nonobviousness, the so-called "secondary considerations." Those relevant indicia include:

- (a) Long felt but unsatisfied need for the invention while the needed implementing arts and elements had long been available;
- (b) Appreciation that a problem existed and what the problem was were theretofore unseen by those skilled in the art;

- (c) Teaching away from the technical direction in which the patentee went by those skilled in the art;
- (d) Unexpectedness of the results of the invention to those skilled in the art; and

See also *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n⁵, 229 U.S.P.Q. 182, 187 n⁵ (Fed. Cir. 1986) (listing the "following tenets of patent law that must be adhered to when applying § 103: (1) the claimed invention must be considered as a whole . . . (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination . . . (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention . . . (4) 'ought to be tried' is not the standard with which obviousness is determined . . . and (5) the presumption of validity remains constant and intact throughout litigation"). See Dunner, ed., "The United States Court of Appeals for the Federal Circuit - Its First Three Years," 13 AIPLA Q.J. 185 (1985); Mintz & Racine, "Anticipation and Obviousness in the Federal Circuit," 13 AIPLA Q.J. 195 (1985).

Most if not all inventions are combinations of known elements; there is solely one standard of nonobviousness for all types of inventions. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 720 USPQ 97 (Fed. Cir. 1983); *Fromson v. Advanced Offset Plate, Inc.*, 720 F.2d 1565, 219 USPQ 1137 (Fed. Cir. 1983); *In re Grasselli*, 713 F.2d 731, 218 USPQ 769 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Environmental Designs, Ltd. v. Union Oil*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983). Chief Judge Markey, writing for the court in *Fromson v. Advanced Offset Plate*, 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985), took the trial court to task for its statement that the patent in suit is a "combination patent comprised exclusively of old elements." Chief Judge Markey observed that "only God works from nothing. Men must work with old elements." Judge Markey cited his article, *Why not the Statute?*, 65 JPOS 331 (1983); the old Testament could properly be relied upon as authority as well.

In ascertaining the differences between the prior art and the claims at issue (the second factual inquiry of *Graham v. John Deere*), it is essential to consider the claims at issue as "the invention as a whole," as required by §103:

a. It is essential to consider all elements of the claimed invention; it is impermissible to compare the prior art with what the viewer interprets the "gist" of the invention to be. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 221 USPQ 669 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1527-28, 220 USPQ 1021, 1024 (Fed. Cir. 1984) ("Reducing a claimed invention to an 'idea', and then determining patentability of the 'idea' is error."). See also, *W.L. Gore & Associates v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *ACS Hospital Systems v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984); *Litton Industrial Products v. Solid State Systems Corp.*, 755 F.2d 158, 225 USPQ 34 (Fed. Cir. 1985).

b. It is impermissible to ignore the advantages, properties, utilities, and unexpected results flowing from the claimed invention; they are part of the invention as a whole. *Fromson v. Advanced Offset Plate*, 755 F.2d 1549, 225 USPQ 26 (Fed. Cir. 1985); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984); *Schenck, A.G. v. Norton Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

The objective indicia of nonobviousness (the "secondary considerations" of *Graham v. John Deere*) are usually the most important items of evidence available and are properly viewed as a "fourth" factual inquiry in the *Graham v. John Deere* investigation. *Simmons Fastener Corp. v. Illinois Tool Works*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984). Finding obviousness through hindsight (i.e., after the fact of the invention and with the teachings of the inventor available) is impermissible and refuted by the objective indicia of nonobviousness. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

Although one may suggest that the structure could readily be modified to form a combination of the claims at issue, the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. Please See in *Re: Gordon* 733 F.

2d 900-902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); *In Re: Grabiak*, 769 F. 2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985).

Therefore, if there is no evidence of motivation in the prior art, either within the reference itself, or knowledge generally available to one of ordinary skill in the art, to make the purported changes to arrive at the claimed subject matter, there is no obviousness.

Further in the *Re Pleuddemann* Decision of August the 3, 1990 before the Court of Appeals, Federal Circuit, 910 F 2d 823, 15 USPQ 2d 1738 the following comment is found:

"In Kuehl the court said, 475 F.2d at 664-665, 177 USPQ at 255:

The test under §103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties. So judged, the process of the appealed claims would not have been obvious. (Emphasis ours).

In the present case likewise, §103 obviousness of claims 26 and 27 depends on the obviousness of using appellant's new compounds, which constitute the essential limitation of the claims, in light of the prior art. That being so, the board's hindsight comparison of the functioning of the new compounds with the functioning of the compounds of the prior art was legal error. It uses appellant's specification teaching as though it were prior art in order to make claims to methods of bonding/priming using his admittedly novel compounds appear to be obvious."

Referring now to the Decision of the Court of Appeals Federal Circuit in *In Re Bond*, decided on August 3, 1990, found at 910 F 2d 831, 15 USPQ 1566, it is stated:

"We are convinced that this holding does not recognize that there are critical differences between the claimed invention and the prior art. See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) (the difference between the claimed invention and the prior art is one of the four factual inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103). It also does not reflect the admonition of this court that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent

some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery and Pro Line Co.*, 804 F. 2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1886); see also *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F. 2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The Board's analysis is a classical example of a hindsight reconstruction of the claimed invention."

In *In re Russell*, 439 F.2d 1228, 1231, 169 USPQ 426, 428 (C.C.P.A. 1971), the Court held that Appellant's position on the law is sound, for even though part of appellant's range of proportions, and all of his ingredients, are suggested by the broad teaching of Wei, if appellant can establish that his relatively narrow range yield unexpectedly superior results as against the broad Wei ranges as a whole, appellant will have established unobviousness of the claimed invention.

Application of Legal Principles Discussed Above

The Examiner has rejected Claims 1-36 under 35 USC §102, as being anticipated by European Patent Application No. 856 313 to Geoghegan et al. ('313), as well as Claims 1-47, 49-59, 61 and 62 as obvious in light of '313.

The Examiner relies on the '313 Patent to assert that the invention claimed by Applicant has been anticipated and is obvious. The Examiner also relies on WO 93/00093 to Deboeck et al. ('093) as obviating Claims 1-61.

Applicant has carefully reviewed the grounds of the Examiner and the prior art references and wishes to submit as follows:

In the first instance the Examiner states that the release rates of the '313 reference overlap those claimed by Applicant, and that Applicant's release range falls within the range disclosed by the '313 reference, specifically at page 3, lines 27-36 of the '313 reference, which provides:

"Those skilled in the art will appreciate that depending on the time of administration throughout the day and the preferred bioprofile to be achieved, products may be formulated with dissolution profiles falling within various subdivisions within the foregoing ranges. A particularly preferred once-daily product normally to be administered prior to bedtime or in the morning upon awakening would be formulated to achieve the following dissolution profile:

- a) from 0 to 35% of the total diltiazem is released after 2 hours of measurement in said apparatus;
- b) from 5 to 45% of the total diltiazem is released after 4 hours of measurement in said apparatus;
- c) from 30 to 75% of the total diltiazem is released after 8 hours of measurement in said apparatus;
- d) from 60 to 95% of the total diltiazem is released after 13 hours of measurement in said apparatus; and
- e) not less than 85% of the total diltiazem is released after 24 hours of measurement in said apparatus."

Furthermore, the Examiner has outlined various other teachings in this reference. Namely,

- (a) the use of a copolymer of acylic and methacrylic acid ester (p. 28, claim 10),
- (b) water soluble polymer can be HPMC (p. 28, claim 7), and
- (c) the core may comprise an organic acid, a lubricant (p. 5, lines 15-29), and other pharmaceutically acceptable components.

The Examiner appears to be using section 2131.03 Anticipation of Ranges from the Manual of Patent Examination Procedures which states:

"When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity" to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. The unexpected results may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP §2131.02. A 35 U.S.C. 102/103 combination rejection is permitted if it is unclear if the reference teaches the range with "sufficient specificity." The examiner must, in this case, provide reasons for anticipation as well as a motivational statement regarding obviousness. Ex parte Lee, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993) (expanded Board). For a discussion of the obviousness of ranges see MPEP 35 § 2144.05.<"

However, in Applicant's respectful submission the Examiner has taken this reference totally out of context and ignored the specific language in the reference and the specific claim language in Applicant's application.

The '313 Patent wholly fails to disclose a chronotherapeutic preparation. While the '313 Patent purports to state that a once-daily product can be administered "prior to bedtime", the '313 Patent does not teach one that would be suitable. One would have to "pick and choose" from the teachings and hope to arrive at such a formulation.

Note particularly that no C_{max} at T_{max} is provided for any formulation in the '313 Patent to that taught by Applicant's invention. For example, Example 14 is based on the preparation of Example 1 and the preparation of Example 1 has a C_{max} of five hours (see Figure 2, curve "a"). This formulation is not a chronotherapeutic formulation. The formulation, when taken by the patient, would provide a C_{max} for the medication at a time not best for the patient (while sleeping after 5 hours) while leaving the patient with a declining concentration in the blood more exposed and vulnerable at a time when the medicine is required most (in the morning). (See Applicant's application, page 1, line 12 to page 2, line 10). Persons skilled in the art would be led directly away from Applicant's invention based on the teachings the '313 reference.

The '313 reference corresponds to United States Patent 5,002,776 listed at page ADA12 of the Approved Drug Products, 20th Edition, with respect to Cardizem CD (a copy of the page is enclosed as Schedule "A"). Cardizem CD is not a chronotherapeutic formulation. This reference is neither an anticipation (a basis for a rejection under 35 USC §102) nor a basis for rejection under 35 USC §103 - obviousness.

With respect to obviousness the Examiner has also taken the position that the further limitations in other claims, i.e. specific amounts of Diltiazem, specific wetting agent, etc., are limitations which would be routinely determined by minimal experimentation, absent the presentation of some unusual and/or

unexpected results. The '313 Patent, however, is "all over the map" and as previously stated one must "pick and choose" if possible (which Applicant denies one can do) to arrive anywhere near Applicant's invention. However, it appears that the Examiner has "picked and chose" based on a hind-sight examination of Applicant's application. This the Examiner is not entitled to do. There is no overlapping.

Furthermore, nowhere in the '313 Patent is there any teaching or any suggestion of how to make a chronotherapeutic preparation. The only teaching in the '313 Patent is that a particular preferred once-daily product may be administered prior to bedtime. (This may be the Example 1 formulation which is not satisfactory - see Figure 2, curve "a".) However, nothing has been given in the '313 Patent to teach a suitable preparation which would act as a chronotherapeutic to be administered prior to bedtime. Applicant's invention has clearly not been described by this prior art and is not obvious in light thereof.

The Examiner also relies on the '093 reference. The '093 Patent corresponds to United States Patent No. 5,529,791 which is listed in the Approved Drug Products 20th Edition with respect to the drug Tiazac at page ADA 13 (a copy of the page is enclosed as Schedule "B"). Tiazac is not a chronotherapeutic product (see Figure 8 of Applicant's application). Neither are other preparations disclosed in the '093 Patent. The Examiner has admitted as much at page 9 of the Official Action:

"WO '093 does not teach the exact rates of release as claimed by Applicant, nor do they discuss the rates of release after 8 hours, nor do they disclose all the specific amounts of the above-mentioned ingredients."

Therefore, the '093 reference does not teach Applicant's claimed invention - the chronotherapeutic preparation providing a C_{max} at the T_{max} and the dissolution profiles which provide the beneficial characteristics. The Examiner, however, takes the position that the '093 Patent teaches overlapping rates of release to those claimed by Applicant. However, the Examiner fails to cite how this

reference teaches the chronotherapeutic formulation of Applicant's invention or how one would achieve it. "Picking and choosing" elements, not all of which are present in '093, does not make Applicant's invention obvious over '093.

Applicant has compared Tiazac™ and an exemplary formulation within the scope of this application. The '093 reference does not teach how one would achieve a chronotherapeutic preparation providing a suitable dissolution profile and C_{max} at the T_{max} of Applicant's invention. The '093 reference does not overlap because it does not teach the "how". Figure 8 of Applicant's Application shows this clearly in "figure form". The Examiner will appreciate that when Tiazac is taken at 8:00 a.m. the C_{max} is about 7 hours after administration (corresponding to the T_{max}). It is only Applicant's formulation as claimed in the instant application which when given, for example, at 10:00 p.m. to midnight would achieve its desired C_{max} between about 10 and about 15 hours after administration.

No other prior art including either the '313 or '093 teaches how to make Applicant's chronotherapeutic formulation. The prior art is discussed in Applicant's Background at pages 2-8. United States Patent No. 5,002,776, corresponding to the '313 reference, is discussed at pages 5 and 6 and the Tiazac listed patent (United States Patent No. 5,529,791, under which Biovail Corporation International (a related company) has a licence) corresponding to the '093 reference is discussed at page 7, lines 15-23.

As the Examiner will now appreciate, the '313 reference is all over the map, makes general statements attempting to deal with all formulations but fails with respect to: (i) chronotherapeutic formulations, and (ii) teaching how to make such a formulation. There is no teaching of Applicant's claimed invention. The same is true with the '093 reference. A "general" imperfect teaching does not make a "specific" teaching. Nor does a general teaching teach a claimed invention where the "how" to achieve Applicant's invention is not described in the prior art references or any reference. Nor does either reference teach Applicant's invention where the reference teaches away from Applicant's

invention as discussed above. Neither the '313 reference nor the '093 reference teaches Applicant's invention or makes Applicant's invention obvious. One would have to "pick and choose" elements and one would still not arrive at Applicant's invention.

In view of the above submissions, Applicant respectfully submits that the Application is in condition for allowance and same is solicited at the earliest convenience.

If the Examiner has any questions, the Examiner is respectfully requested to contact Applicant's Agent, Ivor M. Hughes, or Marcelo K. Sarkis, at (905) 771-6414 (collect) at the Examiner's convenience.

Respectfully submitted,

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Enclosures

1. Formal Drawings (Figures 1-8);
2. Schedule "A" (page ADA12 of the Approved Drug Products, 20th Edition, with respect to Cardizem CD);
3. Schedule "B" (page ADA13 of the Approved Drug Products 20th Edition, with respect to Tiazac);
4. Schedule "C" (examples of patents which have issued with the trademark Eudragit in the claims);
5. Schedule "D" (examples of patents which have issued with the trademark Avicel in the claims);